General

Guideline Title

Syphilis.

Bibliographic Source(s)

New York State Department of Health. Syphilis. New York (NY): New York State Department of Health; 2011 Oct. 18 p. [37 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Syphilis. New York (NY): New York State Department of Health; 2011 Feb. 16 p.

Recommendations

Major Recommendations

The quality of evidence (I-III) and strength of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

What's New — October 2011 Update

Update for *Section II: Prevention*

- Patient education about the risk of acquiring syphilis and other sexually transmitted infections (STIs) from unprotected sexual contact, including all sites of possible transmission, such as anus, cervix, vagina, urethra, and oropharynx

Update for *Section III: Screening and Reporting*

- Nontreponemal testing, such as the rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL), for repeat screening in human immunodeficiency virus (HIV)-infected patients with a history of syphilis infection; the same nontreponemal reagin test should be used when performing repeat screening and when following response to treatment in these patients

Update for *Section V: Diagnosis*

- Lumbar puncture for HIV-infected patients with syphilis or history of syphilis in the following cases:
  - Neurologic or ophthalmologic signs or symptoms are present, including unexplained change in mental status
  - Evidence of treatment failure (as defined in the table footnote below)
  - Evidence of active tertiary syphilis (aortitis, gummas)

- Laboratory dilution and retesting of a negative nontreponemal sample when there is clinical suspicion for syphilis

Update for *Section VI: Treatment and Follow-Up*

- Treatment for primary syphilis in HIV-infected patients if they present with a chancre even in the setting of a preliminary negative nontreponemal screening test
- For penicillin-allergic, HIV-infected patients:
  - Clinician consultation with an expert in infectious diseases and close follow-up if non-penicillin regimens are used to treat syphilis
  - Penicillin desensitization followed by penicillin therapy for neurosyphilis and other forms of tertiary syphilis
  - Penicillin desensitization and treatment with penicillin, rather than use of alternate therapies, if adherence to therapy or close follow-up cannot be ensured

Prevention

Clinicians should counsel HIV-infected patients about the risk of acquiring syphilis and other STIs from unprotected sexual contact, including all sites of possible transmission, such as anus, cervix, vagina, urethra, and oropharynx. (AIII)

When HIV-infected patients are diagnosed with early syphilis (primary, secondary, or early latent), clinicians should intensify risk-reduction counseling, including discussions about the importance of condom use. (AIII)

Screening and Reporting

As part of the annual comprehensive physical examination, clinicians should examine all skin surfaces for lesions, especially in less visible areas, such as the anus, cervix, vagina, urethra, and oropharynx, as well as under the foreskin in uncircumcised males. (AIII)

Clinicians should:

- Obtain serologic screening for syphilis at least annually for HIV-infected patients, and every 4 months for patients with continued high-risk behavior (AII)
- Obtain confirmatory testing if the initial screen is reactive (AII)
- Be familiar with their referring laboratory's syphilis screening algorithm (AIII)

Clinicians should perform a nontreponemal test, such as the RPR or VDRL, for repeat screening in HIV-infected patients with a history of syphilis infection; the same nontreponemal reagin test should be used when performing repeat screening and when following response to treatment in these patients. (AII)

In New York State, clinicians must report suspected or confirmed syphilis diagnoses to their local health department.

Serologic Tests Used for Syphilis Screening

Nontreponemal

- RPR (rapid plasma reagin)
- VDRL (venereal disease research laboratory)

Treponemal

- FTA-Abs (fluorescent treponemal antibody absorbed)
- TP-PA (*T. pallidum* particle agglutination)
- Immunoglobulin G (IgG), treponemal enzyme immunoassay/chemiluminescent immunoassay (EIA/CIA) test (some clinical laboratories and blood banks use the treponemal IgG enzyme-linked immunosorbent assay [ELISA] or EIA assay first, with confirmation by nontreponemal tests).

Presentation

Key Points:

- In the setting of HIV, syphilis may mimic other infections, including herpes and fungal rash, and non-infectious dermatologic conditions, such as psoriasis.
- Syphilitic gumma may present as a focal mass lesion.

- Frequency of clinical relapse after syphilis treatment may be higher in HIV-infected patients, particularly in patients with advanced HIV.

Refer to Table 1 in the original guideline document for information on differences in clinical presentation of syphilis in patients with and without HIV infection.

Diagnosis

Clinicians should include syphilis as part of the differential diagnosis for HIV-infected patients presenting with oral, genital, cervical, or anal lesions, as well as for patients presenting with rash, eye disease, or neurologic disease. Definitive diagnosis is made either by identification of the organism or serologically. (AIII)

Clinicians should perform a baseline neurologic examination for all HIV-infected patients diagnosed with syphilis and should educate patients about the signs and symptoms of neurosyphilis. (AIII)

When there is clinical suspicion for syphilis in an HIV-infected patient, but the nontreponemal test result is negative, clinicians should order laboratory dilution and retesting of the sample. (AII)

Serology

Key Points:

- Serologic test results are negative in patients with incubating syphilis.
- Serologic testing has limited sensitivity during the early primary stage of syphilis (i.e., within the first 10 days after the lesion appears). Use of lesion-based testing or presumptive diagnosis based on lesion appearance may be the only means of diagnosis.

Diagnosis of Neurosyphilis

Clinicians should include neurosyphilis in the differential diagnosis of all HIV-infected patients who present with neurologic symptoms. (AII)

Clinicians should perform a lumbar puncture in HIV-infected patients with syphilis or history of syphilis in the following cases (AII):

- Neurologic or ophthalmologic signs or symptoms are present, including unexplained change in mental status
- Evidence of treatment failure (as defined in the table footnote below)
- Evidence of active tertiary syphilis (aortitis, gummas)

Treatment and Follow-Up

Clinicians should obtain baseline serum nontreponemal reagin level before or at the time of initial treatment for syphilis in order to monitor treatment response. (AI)

Clinicians should treat HIV-infected patients for primary syphilis if they present with a chancre even in the setting of a preliminary negative nontreponemal screening test. (AI)

Clinicians should use long-acting benzathine penicillin G as the preferred treatment for HIV-infected patients with syphilis. Clinicians should ensure that the proper formulations and dosages of penicillin are used. Preparations of long-acting benzathine penicillin G and dosing regimens vary by stage of syphilis and are outlined in the Table below. (AI)

Treating Syphilis in HIV-Infected Patients with Penicillin Allergy

Clinicians should consult with an expert in infectious diseases and provide close follow-up if non-penicillin regimens are used to treat syphilis in penicillin-allergic, HIV-infected patients. (AIII)

Penicillin desensitization followed by penicillin therapy is the treatment of choice for neurosyphilis and other forms of tertiary syphilis. (AII)

Clinicians should desensitize penicillin-allergic HIV-infected patients and treat with penicillin, rather than attempt alternate therapies, if adherence to therapy or close follow-up cannot be ensured. (AIII)

Jarisch-Herxheimer Reaction

Clinicians should inform patients about possible adverse reactions to syphilis treatment, including the Jarisch-Herxheimer reaction. (AIII)

Treatment Failure

Clinicians should evaluate the cerebrospinal fluid (CSF) of HIV-infected patients who experience treatment failure. (AII)

According to the results of the CSF examination, the clinician should either re-treat with therapy for late latent syphilis or initiate parenteral therapy using a recommended regimen for neurosyphilis (see the table below). (AIII) Consultation with an expert in STIs is indicated.

Table: Recommendations for the Treatment and Follow-Up of Syphilis in HIV-Infected Patients

Stage	Treatment[a]	Follow-Up[b]	Comments
Primary, secondary, or early latent	2.4 million units intramuscular (IM) benzathine penicillin × 1 dose	3, 6, 9, 12, 24 months	
Late latent or unknown duration	2.4 million units IM benzathine penicillin per week × 3 weeks	3, 6, 9, 12, 24 months	• Cerebrospinal fluid (CSF) examination recommended only if neurologic, ophthalmologic, or unexplained mental status changes[c]
Gummatous	2.4 million units IM benzathine penicillin per week × 3 weeks	3, 6, 9, 12, 24 months (no data on which to base this)	• CSF examination recommended[c] • Some experts recommend IV therapy as for neurosyphilis
Cardiovascular	2.4 million units IM benzathine penicillin per week × 3 weeks	3, 6, 9, 12, 24 months (no data on which to base this)	• CSF examination recommended[c] • IV therapy as for neurosyphilis recommended by some experts
Neurologic	Aqueous crystalline penicillin G 18-24 million units IV every day (qd) for 14 days	3, 6, 9, 12, 24 months Repeat CSF exam every (q) 6 months until CSF cell count is normal	• Some experts recommend 2.4 million units IM benzathine after parenteral penicillin to have total duration of therapy equal to that of late latent syphilis • CSF abnormalities (elevated total protein and/or positive CSF venereal disease research laboratory [VDRL]) may persist for prolonged periods

[a]The efficacy of non-penicillin regimens in HIV-infected patients is unknown. Penicillin-allergic patients should be desensitized if possible. Alternate treatment regimens should only be used in consultation with an expert in infectious diseases and when close follow-up is ensured.

[b]Follow-up should include a physical examination, neurologic examination, and repeat serologic testing. Treatment failure is defined as development of new clinical signs or symptoms, a 4-fold (2 reagin level) increase in nontreponemal serology (e.g., RPR 1:4 increases to 1:16), or a failure of nontreponemal serology to decline 4-fold (2 reagin levels) by 12 months (nontreponemal serology should decline more rapidly in patients with primary syphilis). Treatment failure in an HIV-infected patient warrants CSF examination, treatment based on results; consultation with an expert in STIs is indicated.

[c]CSF examination yielding pleocytosis, increased total protein, or positive VDRL may be consistent for neurosyphilis.

Management of Partners

Clinicians should consider both HIV and STI exposures to partners when HIV-infected patients present with a new STI. (AIII)

Management of HIV Exposure in Partners

When HIV-infected patients present with a new STI, clinicians should offer assistance with notifying partners of both the potential HIV and STI exposures or should refer patients to other sources for partner notification assistance (Partner Services in New York State or Contact Notification Assistance Program [CNAP] in New York City). Partners without confirmed HIV infection should undergo HIV testing at baseline, 1, 3, and 6 months. Confirmatory testing according to New York State regulations must be performed to confirm HIV diagnoses.

Clinicians should educate patients with non-HIV-infected partners or partners of unknown HIV status to be vigilant for any post-exposure acute HIV symptoms in their partners, such as febrile illness accompanied by rash, lymphadenopathy, myalgias, and/or sore throat (see the New York State Department of Health [NYSDoH] guideline Diagnosis and Management of Acute HIV Infection). (AIII)

Partners who present within 36 hours of an HIV exposure should be evaluated as soon as possible for initiation of post-exposure prophylaxis therapy (see the NGC summary of the NYSDoH guideline HIV Prophylaxis for Victims of Sexual Assault). (AII)

Management of Syphilis Exposure

Clinicians must report all cases of syphilis infections to state and local public health authorities. Clinicians should educate patients with reportable illnesses in New York State about the potential for confidential follow-up from the New York State Department of Health.

Persons exposed sexually to a patient who has syphilis in any stage should be evaluated for oral, vaginal, penile, and anal lesions and serology should be obtained. Clinicians should treat partners with a recommended regimen, according to the following recommendations:

- *For persons who were exposed within the 90 days preceding the diagnosis of primary, secondary, or early latent syphilis in a sex partner*: These persons may be infected even if they are seronegative; therefore, such persons should be treated presumptively. (AII)
- *For persons who were exposed >90 days before the diagnosis of primary, secondary, or early latent syphilis in a sex partner*: Treat presumptively if serologic test results are not available immediately and the opportunity for follow-up is uncertain. (AIII)
- *For long-term sex partners of patients who have latent syphilis*: Evaluate clinically and serologically for syphilis and treat on the basis of the evaluation findings. (AIII)

Definitions:

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Human immunodeficiency virus (HIV) infection
- Syphilis
  - Primary
  - Secondary
  - Latent
  - Tertiary

- Gummatous
- Cardiovascular
- Neurologic

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Screening

Treatment

Clinical Specialty

Allergy and Immunology

Dermatology

Family Practice

Infectious Diseases

Internal Medicine

Neurology

Obstetrics and Gynecology

Ophthalmology

Preventive Medicine

Urology

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

To provide recommendations for the prevention and management of syphilis in human immunodeficiency virus (HIV)-infected patients

Target Population

- Human immunodeficiency virus (HIV)-infected patients co-infected with syphilis
- Partners of HIV-infected patients with syphilis

Interventions and Practices Considered

Counseling/Diagnosis/Prevention/Screening

1. Risk-reduction counseling including education on all sites of possible transmission and of the importance of condom use
2. Screening for syphilis
    - Examination of all skin surfaces for lesions
    - Obtaining a nontreponemal test (rapid plasma reagin [RPR] or Venereal Disease Research Laboratory [VDRL])
    - Verification by fluorescent treponemal antibody absorbed (FTA-Abs) or *Treponema pallidum* particle agglutination (TP-PA)
    - Lesion-based testing
    - Use of same nontreponemal reagin test when performing repeat screening and when following response to treatment
3. Neurological examination
4. Patient counseling about signs and symptoms of neurosyphilis
5. Lumbar puncture and cerebrospinal fluid (CSF) examination if indicated
6. Reporting syphilis diagnosis to local health department

Management/Treatment

1. Long-acting benzathine penicillin G
2. Alternative regimen in penicillin-allergic patients (doxycycline, and possibly ceftriaxone)
3. Desensitization to penicillin and penicillin treatment if alternative regimens are unsuccessful
4. Follow-up (physical examination, serologic tests, CSF evaluation)
5. Management of partners
    - HIV testing
    - Consultation with HIV specialist
    - Evaluation for syphilis lesions and serology testing
    - Long-acting benzathine penicillin G
    - Assistance in partner notification

Major Outcomes Considered

- Sensitivity of serologic tests
- Effectiveness of treatment

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

MEDLINE was searched up to September 2011 with the use of relevant key words. Results were limited to publication years 2006-2011. Epidemiology and statistics of syphilis infection and HIV/syphilis co-infection were updated. Syphilis screening methods that have been recently

introduced in some municipalities were cited, with recommendations for providers about how to interpret these testing protocols and, when applicable, the steps for diagnostic follow-up. Studies were cited to clarify: 1) circumstances when consultation with an infectious disease specialist is recommended; 2) when neurologic syphilis infection should be assessed with lumbar puncture to test cerebral spinal fluid; and 3) alternative treatment regimens for patients with penicillin allergy.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency virus (HIV) infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection

- Committee for the Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Prevention and appropriate management of syphilis in human-immunodeficiency virus (HIV)-infected patients and their partners

Potential Harms

- Nontreponemal tests may render false-positive or false-negative results. Serum samples containing large amounts of nontreponemal reagin occasionally demonstrate a false-negative reaction, known as a prozone reaction. When there is clinical suspicion for syphilis but the nontreponemal test result is negative, clinicians should order laboratory dilution and retesting of the sample. Nontreponemal tests may be positive in the setting of medical conditions other than syphilis, including human immunodeficiency virus (HIV) infection, collagen vascular disease, narcotic drug use, advanced age, pregnancy, chronic liver disease, and some viral infections, such as Epstein-Barr virus, and other chronic inflammatory conditions (i.e., biological false-positive nontreponemal test).
- The Jarisch-Herxheimer reaction, which is caused by the immunologic response to the destruction of the spirochete, can occur within the first 24 hours of syphilis therapy and may require acute management. This acute febrile reaction is frequently accompanied by headache, myalgia, and/or worsening of secondary syphilis rash, and occurs most often in patients with early syphilis. The Jarisch-Herxheimer reaction

may induce early labor or cause fetal distress in pregnant women; but this concern should not prevent or delay therapy.
- Resistance and treatment failures have been documented with the use of azithromycin (2 g PO in a single dose) for early syphilis; this agent should be used with caution and only when treatment with penicillin or doxycycline is not feasible.

Qualifying Statements

Qualifying Statements

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

Implementation of the Guideline

Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with HIV infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

New York State Department of Health. Syphilis. New York (NY): New York State Department of Health; 2011 Oct. 18 p. [37 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2009 Jan (revised 2011 Oct)

Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

Source(s) of Funding

New York State Department of Health

Guideline Committee

Medical Care Criteria Committee

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Syphilis. New York (NY): New York State Department of Health; 2011 Feb. 16 p.

Guideline Availability

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site .

Availability of Companion Documents

The following are available:

- HIV and sexually transmitted infections. CME course. Available from the Clinical Education Initiative Web site .
- NYSDoH syphilis guidelines: a case presentation. CEM course. Available from the Clinical Education Initiative Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 5, 2010. This NGC summary was updated by ECRI Institute on January 30, 2012.

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